4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0008]

# Device Good Manufacturing Practice Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Device Good Manufacturing Practice Advisory Committee. The committee reviews regulations proposed for promulgation regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations to the Commissioner of Food and Drugs regarding the feasibility and reasonableness of those proposed regulations. The meeting will be open to the public.

DATES: The meeting will take place virtually on March 2, 2022, from 9 a.m. to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability may be accessed at: https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings.

FOR FURTHER INFORMATION CONTACT: Jarrod Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002, Jarrod.Collier@fda.hhs.gov, 240-672-5763, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC

area). A notice in the *Federal Register* about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at https://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting. The meeting will be webcast and will be available at the following links: YouTube (primary): https://youtu.be/SPrNfVb2Yv8 and TEAMS (captions): https://teams.microsoft.com/. Please log on 20 minutes before the webcast to test your signal. You may have to refresh your browser before logging on.

SUPPLEMENTARY INFORMATION:

*Agenda*: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. As required by section 520(f)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD& C Act) (21 U.S.C. 360j(f)(1)(B)), on March 2, 2022, the committee will discuss and make recommendations on the current good manufacturing practice requirements for medical devices under 21 CFR part 820, the Quality System Regulation, to align more closely with an international consensus standard for medical devices used by other regulatory authorities.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at https://www.fda.gov/advisory-committees/medical-devices/device-good-manufacturing-practice-advisory-committee. Select the link for the 2022 Meeting Materials. The meeting will include slide presentations with audio components to allow

the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 24, 2022. Oral presentations from the public will be scheduled on March 2, 2022, between approximately 1:30 p.m. to 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see FOR FURTHER INFORMATION CONTACT). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 21, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 22, 2022.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at AnnMarie.Williams@fda.hhs.gov or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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